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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,599	05/26/2000	James M. Zavislan	ML-0362C2	8050

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Kenneth J Lukacher  
South Winton Court  
3136 Winton Road South Suite 304  
Rochester, NY 14623

EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3739

24

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/579,599

Applicant(s)

ZAVISLAN ET AL.

Examiner

Ahmed M Farah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 27-31 and 33-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-31 and 33-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6.14.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 27-31, 33-36, 44, 45 and 47-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Charles J. Koester "Scanning mirror microscope with optical characteristics: applications in ophthalmology." Appl. Opt. Vol. 19, No. 11, June 1980.

Koester teaches a method and apparatus for examining a number of biological tissues using incident light microscopy. Fig. 2 of Koester shows a microscopic imaging apparatus for pathological applications, the apparatus comprising: a) an objective lens, b) a window, which has a surface capable of being in pressure contact relationship with the surface of a tissue sample, c) an illumination beam, which is focused by the objective lens through the window to the tissue sample, and d) a return signal, from the tissue sample, which carries pathological information of the sample. In reference to claim 31, Koester's window is transparent to the illumination light.

With respect to claim 33, he teaches that the numerical aperture of the objective lens is selected based on the area being viewed. See equation 2.

As to claim 34, he teaches a display means for displaying a tissue section being examined (see Fig. 8).

As to claims 35 and 36, the applicant recites intended use of the apparatus. These claims fail to recite structural and/or functional limitations of the apparatus. Therefore, they are not given a patentable weight. Furthermore, the device of Koester is capable to analyze tumorous tissue as presently claimed.

In paper No. 11, filed on April 9, 2002, the applicant argues that the instrument of Koester is not a handheld unit. In response to this argument, the device of Koester is designed to be placed on the corneal tissue of the eye. Therefore, the examiner's position is that such a device is small enough to be a handheld unit.

3. Claims 27-31, 44, and 47-48 rejected under 35 U.S.C. 102(a) as being anticipated by Maurice D. "Cellular Membrane Activity in the Corneal Endothelium of the Intact eye," *Experientia*, Vol. 24, pp. 1094-1095, (1968).

Murice shows a microscopic imaging apparatus for pathological applications, the apparatus comprising: a) an objective lens, b) a window, which has a surface capable of being in pressure contact relationship with the surface of a tissue sample, c) an illumination beam, which is focused by the objective lens through the window to the tissue sample, and d) a return signal, from the tissue sample, which carries pathological information of the sample. In reference to claim 31, Maurice's window is transparent to the illumination light.

4. Claims 27, 28, 30, 31, 44, 45, and 47-48 rejected under 35 U.S.C. 102(a) as being anticipated by Maekawa et al. JP 8-140961.

Maekawa et al. disclose a microscopic imaging apparatus for imaging a tissue sample for pathological applications through an objective lens **30**, the apparatus comprising:

an objective lenses **32**;

a window **16** having a surface capable of being pressed into a contact relationship with the surface of a tissue skin **16**, said window being in optical communication with said objective lens;

a housing **58** inclosing at least said objective lens **32** and said window **16**, said housing capable of being handheld; and

a video recorder **50** for storing and displaying the diagnostic results received from the analyzation means **70** as presently claimed.

As to claim **28**, the illumination beam is focused onto the tissue by the objective lens **32** as presently recited.

As to claim **30**, the apparatus further comprises an illumination means **22**, which provides an illumination beam that is focused to the tissue sample by the objective lens **32** through the transparent window **16**.

As to claims **31**, **44** and **48**, the window is transparent to the illumination light and it is pressed against the tissue sample without use of suction (negative pressure) as presently claimed.

Claims **27**, **28**, **30**, **31**, **44**, **45**, and **47-48** rejected under 35 U.S.C. 102(a) as being anticipated by Ishihara et al. EP 0 683 386 A1.

Ishihara et al. disclose a microscopic imaging apparatus for imaging a sample for pathological applications through an objective lens **30**, the apparatus comprising:

an objective lenses **32**;

a window **16** having a surface capable of being pressed into a contact relationship with the surface of a tissue skin **16**, said window being in optical communication with said objective lens;

a housing **58** inclosing at least said objective lens **32** and said window **16**, said housing capable of being handheld; and

a video recorder **50** for storing and displaying the diagnostic results received from the analyzation means **70** as presently claimed.

As to claim **28**, the illumination beam is focused onto the tissue by the objective lens **32** as presently recited.

As to claim **30**, the apparatus further comprises an illumination means **22**, which provides an illumination beam that is focused to the tissue sample by the objective lens **32** through the transparent window **16**.

As to claims **31**, **44** and **48**, the window is transparent to the illumination light and it is pressed against the tissue sample without use of suction (negative pressure) as presently claimed.

5. Claims **27-36** and **44**, **45**, **47**, and **48** are rejected under 35 U.S.C. 102(b) as being anticipated by Harris U.S. Patent No. 5,120,953.

Harris discloses a scanning confocal microscope comprising: a light source for supplying illumination light; a focusing lens, which focuses the light to the tissue being

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examined; and a window that is transparent to both the illumination light from the light source and back-scattered/return light from the tissue being examined. Fig. 10 of Harris shows that the window is in pressure contact with the tissue **107** being examined (the hard tissue). Harris further teaches that the return signal from the sample tissue is viewed by imaging means **37**.

In this Office Action, the opening of handpiece **101** in which the objective lens **110** is disposed is treated as the window (see Fig. 10). This window is transparent to both the illumination light and the backscattered light. Furthermore, the walls of this window are pressed against the dental tissue being examined as recited in the amended claims (Paper No. 23, filed on Dec. 15, 2003).

As to claims 29 and 34, the objective lens **110** receives the return light from the tissue sample being examined.

As to claims 35 and 36, the applicant recites intended use of the apparatus. These claims fail to recite structural and/or functional limitations of the apparatus so as to further limit the prior claims. Hence, the examiner's position is that the device of Harris is capable to diagnose cancerous tissue as presently claimed.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 37-43 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maekawa et al. in view of Hochman et al. U.S. Patent No. 5,699,798.

Maekawa et al. teach the limitations of the instant claims except a method for diagnosing a tumor as presently recited. However, Hochman et al. teach an alternative apparatus and method for diagnosing a tumor by using an imaging microscope (see the abstract and Example 5, col. 21, line 38 through col. 22, line 6).

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify the teachings of Maekawa et al. in view of Hochman et al. to use the microscopic device for diagnosing a tumorous tissue. The use of microscopic devices for tissue diagnosis, including cancerous tissue, is well known in the medical art.

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M Farah whose telephone number is (703) 305-5787. The examiner can normally be reached on Mon-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M DVorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Farah



02/22/04